1. PURPOSE
   1. This guidance establishes the University at Buffalo definition of a case report and the review required.
   2. The process begins when the principal investigator (PI) meets the requirements of the definition of a case report
   3. The process ends when the case report is accepted for publication.
2. REVISIONS FROM PREVIOUS VERSION

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| **Version** | **Date** | **Revisions** |
| R00 | 12/4/2020 | Original issue |
| R01 | 12/17/2020 | Annual review, correct typo, update logo |
| R01 | 10/8/21 | Annual review, no changes |
| R01 | 11/14/23 | Annual review, no changes |

1. POLICY
   1. The UB IRB defines a case report as a retrospective analysis of one, two, or three clinical cases.
   2. If more than three cases are involved in the analytical activity, the activity will constitute “research.”
   3. A case report is a medical/educational activity that does not meet the DHHS definition of “research”, which is: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."  Therefore, the activity does not have to be reviewed by the IRB.
   4. Although IRB review and approval is not required, certain HIPAA Privacy Rule requirements apply to the use and disclosure of PHI for a case report:

* Investigators that remove HIPAA identifiers from the case report data prior to disclosure of the data (e.g., prior to submission of the case report to a journal) do not need to obtain a signed privacy authorization from the subject.

Please note that in addition to removing the 18 listed HIPAA identifiers, the investigator must determine that no photo or illustration in the case report could lead to identification of the subject(s), and that the case(s) described are not so unique as to be identifiable with reference to other public sources such as media accounts.

* Investigators who publish a case report that is not completely de-identified to the standards of the HIPAA Privacy Rule (i.e., that contains any direct or indirect identifiers), must first obtain each subject’s signed HIPAA-compliant authorization.  It is not necessary to submit this authorization form to the IRB for review.

**Please Note: If your data is collected at an institution that has its own Privacy Office, it is the responsibility of the investigator to contact the Privacy Officer of that institution to confirm that all of their regulations are met.**

**DEFINITION OF DE-IDENTIFIED DATA**

**Identifiers That Must Be Removed to Make Health Information De-Identified**

(i) The following identifiers of the subject(s) or of relatives, employers or household members of the individual must be removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

1. Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

1. RESPONSIBILITIES
   1. It is the responsibility of the investigator to confirm that the definitions of a case report are met.
   2. It is the responsibility of the investigator to submit their work to the IRB before submission for publication if there is any doubt that it meets the definition of a case report.
   3. It is the responsibility of the investigator to confirm that the case report meets HIPAA requirements and is reviewed by the local privacy officer before submission for publication if any personal Health information and/or personal identifiers are present.
2. PROCEDURE
   1. The investigator must confirm that the work meets the UB definition of a case report or submit to the IRB for a formal determination.
   2. If the case report is not deidentified and includes any PHI or personal identifiers, the investigator must contact their local Privacy Officer to discuss their required steps prior to publication.

NOTE: Case reports for publication must be prepared in accordance with the requirements of the HIPAA privacy regulations. Any use or disclosure of PHI must be authorized by the subject, or, if the subject is deceased, the subject’s family. Publication of a case report containing PHI is a disclosure of PHI. The Privacy Officer or designated HIPAA authority at the applicable organization should be consulted prior to submission of the case report to assure proper authorization was obtained.

* 1. Although the use of protected health information to publish the case report does not require IRB review, the author of the case report must comply with HIPAA.
     1. Ideally, the author of the article will obtain the signed authorization of the subject, or the subject’s legally authorized representative if the subject is deceased, to use the subject’s information in the report regardless of whether it is deidentified..
     2. If it is not possible to obtain authorization, the author should be aware that one of the identifiers described by HIPAA as requiring written authorization is, “Any other unique identifying number, characteristic, or code….”
     3. Moreover, HIPAA requires that, at the time of publication, “[t]he covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.”
  2. Once an investigator has confirmed that the proposed submission meets the UB definition of a case report and all HIPAA requirements have been satisfied, it can be submitted to a journal with the UB IRB memo (HRP-911)
     1. If a journal does not accept the IRB memo, the investigator should inform the UB IRB and the work will be reviewed by the IRB for resolution.